4.2 Management System

4.2.1 The laboratory management system is outlined in the following documents:

- Quality manual,
- Written procedures,
- Work Instructions,
- References, and
- Forms and records.

This management system is established to address the requirements in ISO/IEC 17025. Each entity establishes and maintains a master list of procedures per the procedure for document control. The quality policy and quality objectives for ORA laboratories are included in Volume 1, subsection 4.2.2. The documents listed above are accessible to all personnel and are included in the laboratory's training program.

4.2.2 Management System Policy

Mission

ORA's mission statement states "ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products". FDA laboratories are committed to providing testing that meets both the needs of the customers and the requirements of ISO/IEC 17025 and to continually improve the effectiveness of the management system. Testing results are reported within stated limits of accuracy, precision, and detection limits as described in the methods used for analysis.

Commitments to Quality Issued by Director, Office of Regulatory Science

4.2.2 a. Good Professional Practice and the Quality of Testing

ORA laboratories are committed to the Standards of Ethical Conduct which define the obligations of public service issued under Executive Order 12674. Testing is conducted according to the policies stated in Volume I, subsections 5.4**;** 5.7. The laboratory management and personnel are committed to performing quality activities to assure integrity, accuracy, precision, reliability and timeliness of the data.

4.2.2. b. Standard of Service

The laboratory's standard of service for the testing program is defined by the ISO/IEC 17025 requirements, FDA regulatory needs included as part of the laboratory methods, and the following:

- Established and maintained documented procedures for laboratory operation based upon consensus methods for testing. Methods are specified or cited in the compliance program and compendiums, or by the customer. In some cases, testing and procedures as established by the instrument manufacturer are used.

- Sample handling and management procedures to maintain integrity of both the samples and the documentation to support the analytical data.

- Maintenance of records in such manner that facilitates retrieving them later. Records are maintained in the analyst worksheet packet filed by sample number. Records may be archived on- or off-site depending on the home district of the collector. Archival retention periods are stated in the laboratory's record management procedure.

- Employment of qualified and trained personnel to perform the tasks to support the laboratory objectives. Performance demonstrations by technical personnel conducting laboratory methods are conducted and documented.

- Routine maintenance of quality control data to support testing results by demonstrating that measurement processes are maintained in statistical control. Accuracy and precision control charts are used to monitor performance.

- Maintenance of an instrument calibration program that provides measurement traceability to International System of Units (SI) units. This is accomplished with the use of national, international, or industry accepted standards of measurement.

ORA laboratory personnel follow the policies included in this Volume, the processes described in their local operating procedures, and the processes described in laboratory methods referenced in this Volume.

Changes to management system documents are made according to the laboratory document control procedure and involve periodic revisions of this Volume.
An internal audit process is used to evaluate the effectiveness of the management system established for laboratory operations. It is the policy of ORA laboratories to participate in

interlaboratory proficiency programs as these are announced and as requested by the accrediting body.

The sections in this Volume describe elements and reference procedures that outline the management system established to accomplish the mission of the laboratory.

Test reports and the communication of information generated by the laboratory are conducted under the direction of the Laboratory Director.

The operational procedures for the laboratory are listed in its master list**,** as described in the laboratory's document control procedure**.**

4.2.2 c. Management System Objectives

The primary objective of the management system established by ORA laboratories is to assure the accuracy and precision of laboratory results so that they will be reliable, interpretable, repeatable, and defensible. Data quality objectives are described in the terms of:

- accuracy,
- precision,
- detection and quantitation limits,
- timeliness, and
- comparability.

The second objective is to establish and maintain national and international recognition through compatibility with the requirements of relevant standards.

Third, strive to meet or exceed the customer's needs and expectations for precision, accuracy, sensitivity, and specificity.

Fourth, maintain ORA laboratories' reputation for quality by fostering continuous process improvement and problem prevention.

These objectives are taken into account as part of the reviews performed by management.

4.2.2 d. Management System Awareness and Implementation

The management system documents and test methods are included as training elements in the laboratory's training program addressed in the laboratory training procedure. This ensures that staff is familiar with quality documentation and implement the quality

policies and procedures in their work. See template, Volume II, Section 2, ORA-LAB.5.2 Personnel: Training Procedure.

The implementation of the quality policies is evidenced by the manner in which work activities are conducted. Implementation of the management system procedures is evidenced by the generation of required records. The audit and management review activities are the mechanisms that are used to monitor the implementation effort of the laboratory management system.

4.2.2 e. Commitment to ISO/IEC 17025.

The policies for operation of the laboratory management system are established to address the requirements of ISO/IEC 17025. ORA laboratories are committed to laboratory accreditation according to the requirements of ISO/IEC 17025. This commitment is evident by the approval signatures by each Laboratory Director for this quality manual.

4.2.3 Evidence of management's commitment to the management system and its continual improvement in effectiveness is demonstrated by but not limited to participation of managers in the management reviews, performance of internal audits, proficiency testing, and the analysis of quality control samples.

4.2.4 Effective communication from management occurs through the use of but not limited to memos, newsletters, electronic presentations, emails, or verbally to laboratory personnel regarding the importance of meeting customer, statutory, and regulatory requirements.

4.2.5 Procedures and Outline of the Management System

Management system procedures supporting quality policies are cited in the Related Procedures at the end of each section of this Volume. The outline of the management system is included in Volume I, Subsection 4.2.1. Where needed, each laboratory shall have procedures to implement the quality policies at the local level and include these procedures in its Master List. Laboratories shall include a reference to the corresponding requirements in this Manual.

4.2.6 Roles and Responsibilities

General roles and responsibilities for ORA laboratory personnel are summarized as follows:

- Quality System Manager
  - — Ensures that the management system is established, implemented, and maintained in conformance with the requirements of ISO/IEC 17025.

— Advocates and coordinates quality improvements to the management system.

- Responsible Managers (technical management)
  - — Oversee technical functions.
  - — Ensure compliance with the requirements of ISO/IEC 17025.
  - — Ensure management system procedures, applicable standards, specifications, and regulations are followed.
  - — Ensure that qualified, skilled, and trained personnel and other resources are available.
  - — Ensure that products and services satisfy customer requirements.

- Analysts
  - — Ensure the quality of their work.
  - — Operate in conformance with the requirements of the management system.

4.2.7 The management system process and procedures as defined in this manual maintain the integrity of the management system when changes such as a change in the structure of the organization or management, or a change is a policy or procedure are made.